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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/445,205	01/07/00	GALZI J	97AHCNRFLU

000466 HM12/0117
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EXAMINER	
SISSON, B	
ART UNIT	**PAPER NUMBER**
1655	9

DATE MAILED: 01/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary	Application No.	Applicant(s)	
	09/445,205	GALZI ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *1-9,22-26 and 29-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-21,27,28 and 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *7 January 2000* is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II in Paper No. 7 is acknowledged. The traversal is on the ground(s) that a search of Group I along with that of Group II would not place an undue burden on the Office. This is not found persuasive because a search of Group I would also include a search of numerous, specified sequences that are not recited in Group II.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-9, 22-26, and 29-31 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

3. Claims 32-34 will be examined along with the claims of Group II.

Claim Objections

4. A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.

5. A claim that depends from a dependent claim should not be separated by any claim that does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In the present case dependent claims 12-21 are separated from their parent, or independent, claim 10 by independent claim 11. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

6. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

7. The attempt to incorporate subject matter into this application by reference to a variety of published journal articles in claims is improper because 10 only issued US patents may be incorporated by reference when they disclose essential material; and 2) the articles recited seemingly teach critical aspects of the claimed invention and as such , the public must rely upon these articles either to practice the invention or to more clearly identify the metes and bounds of the claimed invention.

Drawings

8. The drawings are objected to for reasons as stated on FORM PTO-948 (Rev. 8-98). Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the examiner allows the application.

Specification

9. The disclosure is objected to because of the following informalities:

a. The disclosure has been found to contain representations of nucleotide sequences that are not accompanied with the requisite SEQ ID NO.

b. The specification does not begin with a paragraph that indicates any claim to benefit or priority.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 10-21, 27, 28, and 32-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As presently worded, the method of claims 10-21, 27, 28 and the kit of claim 32 all require the use or availability of any possible variant of GFP that a) conserves the fluorescent property of GFP, or conserves the fluorescent property and its ligand labeled with a fluorescent substance. The specification does not reasonably suggest that applicant was in possession of any and all manner of variants that have the requisite properties. Further, the specification does not

reasonably suggest that applicant was in possession of a method that would allow for the detection and quantitation of any ligand (claims 10-21 and 27), nor for the identifying and quantifying any such ligand (claim 28). In support of this position, attention is directed to the decision of *Vas-Cath inc. V. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

Kit claims also have been found to encompass plasmids that comprise a polynucleotide sequence that encodes any and all possible target proteins, known and unknown, as well as any and all possible ligands-coding polynucleotide sequences, and variants thereof. The specification has not been found to reasonably suggest that applicant was in possession of these myriad constructs at the time of filing.

12. Claims 10-21, 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It would appear that applicant is relying upon the public to identify and produce the reagents (target proteins and ligands) envisioned for the now claimed method and to also determine the appropriate conditions under which the claimed methods are to practiced. This is equally applicable to the "detecting and quantifying" assays as well as for the "identifying and

quantifying" assays. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research.

For the above reasons, and in the absence of convincing evidence to the contrary, the specification has not been found to satisfy the requirements for written description and enablement as set forth in 35 USC 112, first paragraph.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 10-21, 27, 28, and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10-21, 27, 28, and 32-34 are confusing as a result of the use of indentations. It is not readily what is associated with what as seemingly that which should be further indented is at the first level of indentation.

15. Claim 10 recites the limitation "the target protein" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claims 12-21, which depend from claim 10, fail to overcome this issue and are similarly indefinite.

16. Claim 10 recites the limitation "the gene" in line 5. There is insufficient antecedent basis for this limitation in the claim. Claims 12-21, which depend from claim 10, fail to overcome this issue and are similarly indefinite.

17. Claim 10 is confusing where in line 26 the word "either" is used yet it is not readily apparent what the alternative is, especially in view of the like levels of indentation and the compound use of "either" as seen in line 29.

18. Claims 10-21, 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

a. Those steps needed to bring the reactants into close proximity with one another so to permit binding;

b. Those steps which would serve to remove unreacted components;

c. Those steps which allow for a standardization;

Those steps which would allow for the quantitation of any target protein with any ligand.

19. Claims 10 and 11 are indefinite as a result of the phrase "in particular of the receptor." It is not readily apparent if the claim is to be limited to receptors only or other target proteins are to be included. Claims 12-21, which depend from claim 10, fail to overcome this issue and are similarly indefinite.

20. Claim 14 is indefinite with respect to the inclusion of bibliographic citations within the body of the claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1655

BLS
January 12, 2001